

MAR 14 2001

Section 807.87(h) 510(k) Summary

Date of preparation: January 31, 2001

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

A. REASON FOR 510(k): Introduction of a new product.

B. NAME OF DEVICE:

<u>Proprietary Name:</u>	Innovo®
<u>Classification:</u>	Syringe Piston
<u>Common or usual name:</u>	Insulin Delivery Device
<u>Class:</u>	Class II

D. ESTABLISHMENT REGISTRATION NUMBER:

E. SUBMITTER'S NAME AND ADDRESS:

Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, New Jersey 08540

Contact person: Robert Fischer
Tel: 609-987-5891
Fax: 609-987-3916

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F. MANUFACTURING FACILITIES:

Novo Nordisk A/S
Medical Systems
Brennum Park
DK-3400 Hillerød
Denmark
Tel: 45 44 44 88 88
FDA Device Establishment Registration Number: 9027307

G. PERFORMANCE STANDARD(S):

No performance standards applicable to piston syringe devices or similar products have been established under Section 514 of the Food, Drug and Cosmetic Act. The Innovo® device will be manufactured in accordance with current Good Manufacturing Practices for Medical Devices.

H. DEVICE DESCRIPTION AND INTENDED USE:

Description

Innovo® is a combined mechanical/electronic device for delivery of insulin from 3 mL insulin cartridges. The device is used with PenFill® 3mL cartridges containing insulin and NovoFine® needles.

Innovo® is operated manually which means that dose setting and injection of the insulin dose is performed manually. The injection technique used is the same as that used with presently available "pen-like" insulin injection devices.

The Innovo® Dial-a-Dose Insulin Delivery Device is a syringe piston. The Innovo® is made of

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stainless steel, brass and plastics, similar to other various commercially marketed syringe piston injectors, which operate on the same principles.

Innovo has a digital display with an electronic memory function powered by a non-replaceable lithium battery.

I. SUBSTANTIAL EQUIVALENCE

The Innovo® is substantially equivalent to Novo Nordisk's NovoPen 3 device, submitted originally as a 510(k) application, #K965148, on December 20, 1996, requested by FDA to be withdrawn and re-submitted as a supplement to Novolin® R NDA #19-938 (S-021) with cross-reference to Novolin® N NDA #19-959 (S-022) and Novolin® 70/30 NDA #19-991 (S-022). The re-submission was filed on January 29, 1997 and the NDA supplements approved on June 20, 1997.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the court.

Barry Reit
Barry Reit, Ph.D.

Vice President, Regulatory Affairs
Novo Nordisk Pharmaceuticals Inc.

2/2/01
Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2001

Mr. Robert Fischer
Associate Director of Regulatory Affairs
Novo Nordisk Pharmaceuticals, Incorporated
100 College Road West
Princeton, New Jersey 08540

Re: K010359
Trade Name: Innovo
Regulatory Class: II
Product Code: FMF
Dated: February 2, 2001
Received: February 6, 2001

Dear Mr. Fischer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

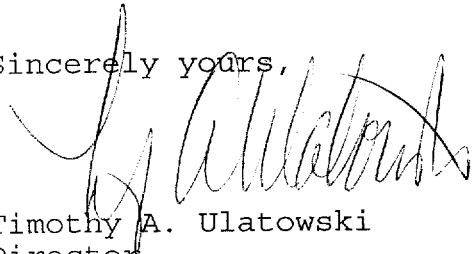
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not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 801.109 Indication for Use Statement

Applicant: Novo Nordisk Pharmaceuticals, Inc.

510(k) Number (if known): ~~Not Applicable~~ K010359

Device Name: Innovo®

Indications for Use: The Innovo® device is used for subcutaneous administration of insulin for treatment of individuals with diabetes mellitus.

(Division Sign-Off) *[Signature]* for PxC 3/14/01
Division of Dental, Infection Control
and General Hospital Devices
Device Number K010359

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(PART 21 CFR 801.109)

(Optional Format 1-2-96)